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Chapter

Present Challenges of Robotics in Gynecology

Pranjal H. Desai and Ryan J. Gillentine

Abstract

Hysterectomy is one of the most common operations performed in gynecology. In the last decade and a half, the da Vinci robotic system has gained widespread acceptance in gynecology due to enhanced visualization and excellent dexterity compared to conventional laparoscopic techniques. The rapid adoption of the technology comes with unique challenges. Excluding initial acquisition cost and maintenance cost, surgery performed robotically is expensive than laparoscopic surgery. Higher cost on each case questions many about the viability of the robotic platform. Several hospitals have successfully established the robotic program, but many are reluctant to acquire expensive technology, and some are rolling back on their decision due to various reasons. This chapter expands on those challenges, mainly needs assessment, team building, culture of safety, learning curve, business strategy, and return of investment.

Keywords: Robotic hysterectomy, need assessment, team building, learning curve, culture of safety, business model

1. Introduction

Hysterectomy is the surgical procedure to remove the uterus surgically. The word 'Hysterectomy' is invented based on Ancient Greek hustéra, "womb" and ektomía- "a cutting out of," and, thus, means the removal of the uterus. Hysterectomies can be performed by open incision, vaginally, or minimally invasively—either by laparoscopy or robotically. Around 600,000 hysterectomies are performed in the United States annually [1]. Out of them, 85% are for non-cancerous lesions [2]. The traditional open approach to perform hysterectomies involves making a large incision around 10–15 cm above the pubic bone horizontally or vertically. Studies have demonstrated that hysterectomies with open approaches have higher blood loss, increased average length of hospital stay, and more postoperative complications in comparison to minimal invasive approach, including laparoscopic and robotic. The laparoscopic approach has been used for more than three decades and has become standard of care for many gynecological procedures. In 2005, the US Food and Drug Administration approved the use of the da Vinci robotic system for gynecologic surgeries. The use of this technology has allowed surgeons to perform gynecologic procedures with improvements in visualization, including 3D stereoscopic visualization, increased range of motion with enhanced wrist movements, and improved ergonomics with excellent dexterity compared to conventional laparoscopic techniques [3, 4]. However, studies have not shown any difference in operative or postoperative outcomes for patients undergoing robotic hysterectomies compared to laparoscopic hysterectomies [5, 6]. The robotic approach, indeed, has longer operative times [7] for certain operations and is more expensive, not exclusively limited to only operative cost (6–25% more than laparoscopy) [8] but also initial acquisition cost and maintenance cost compared to the standard laparoscopic approach [9]. The da Vinci system requires an initial investment of $1.5 to $2.5 million, depending on the model and configuration. Ongoing costs include annual service contracts (ranging in price from $150 to $170 K), instrument and accessory costs (ranging from $700–$3,500 per procedure).

Despite all shortcomings, surgeons still appreciate excellent visualization providing [6] more precision in surgery and better ergonomics, allowing them to do certain complex tasks, which would be very difficult with standard laparoscopic procedure. Many studies have shown the utility of the robotic platform with better outcomes and safety profiles for various benign conditions, including robotic myomectomies [10] for fibroids, robotic-assisted laparoscopic sacrocolpopexy for pelvic organ prolapse, endometriosis, benign ovarian tumors, etc. [7, 10]. The role of minimally invasive surgery for endometrial cancer has been well established by LAP 2 study [11, 12]. In addition, the role of robotic platform for other gynecological cancer including early cervical and ovarian cancer have been investigated as well [13]. In 2012, the Clinical Practice Robotics Task Force of the Society of Gynecologic Oncology stated that robotic-assisted surgery in the field of gynecology-oncology provides an advantage over traditional methods, including conventional laparoscopic approaches and laparotomies [14]. The use of robotic platform has been well established in many gynecological procedures and in other specialties like general surgery, urology, cardiothoracic surgery, etc. However, with higher acquisition and maintenance costs and with no difference in reimbursement compared to the standard laparoscopic procedure, many small community hospitals that initially acquired a robotic platform by using all cash reserves are struggling to keep it going, and many are rolling back on their decision in 1–3 years [8, 15]. In addition to a higher financial burden, many other factors are roadblocks for widespread implementation or failures of robotic programs. In this article, we would like to expand further on these roadblocks and provide reasonable, evidence-based solutions.

2. Need assessment

Prior to the acquisition of highly expensive robotic technology, 'Need Assessment' is an imperative step for hospitals, especially small community hospitals with limited cash reserve. Despite the rapid rise of robotic surgery, its usefulness, mainly attributed to cost concern in gynecological surgeries, has been questioned by many [16]. However, to compete with the current market and other hospitals, regional hospitals have to enter into a 'medical arms race" to acquire a robotic platform [17]. Since more and more trainees graduating from residency programs are trained on a robotic platform, small community hospitals view da Vinci as a survival tool to retain and/or recruit surgeons which will keep them in business. It is not an uncommon belief among administrators that a robotic platform can be used as a marketing tool to attract more patients. Medicare in the US helps to absorb the partial cost of robotic systems for critical access hospitals based on the number of the patients on Medicare using those facilities. However, that partial cost may still be too much for the small community hospital with scarce resources to spend. Therefore, they should have to have a thorough 'need assessment' to determine whether the purchase of a robotic system is worth a 'buy.' 'Need Assessment' is a standard industry procedure routinely being carried out in large businesses to analyze the 'need,' which is the gap between the current condition and the desired

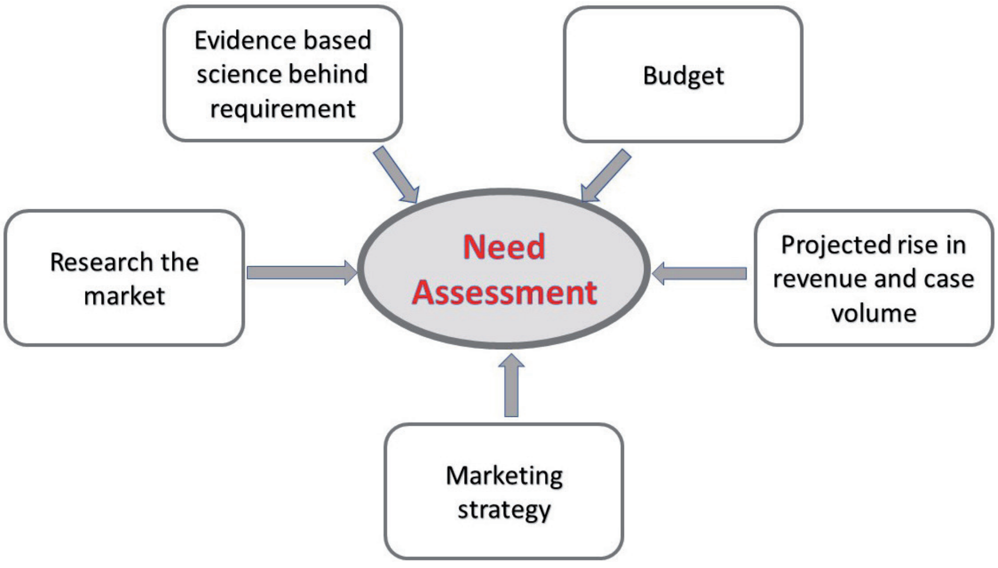

Figure 1.
Important factors for need assessment.

condition. Need assessment to acquire costly surgical instruments is a multistep process [18] including confirmation of necessity or define the need to acquire technology from surgeons based on evidence-based science, research the market, budget, projected rise in revenue, and room for a potential marketing strategy to increase payer mix. It is essential that hospitals should investigate the readiness of their surgeons to get trained, or hospitals should be recruiting new surgeons who are already trained. Many hospitals hire independent agencies to perform market research and viability analysis to find a sweet spot. Regardless, market research involving a rise in case volume by getting new patients who may otherwise travel far to undergo robotic procedure and internal research to determine the proportion of current surgeries which can be performed using a robotic platform are two extremely important data points in decision making. Balancing resource spending and budgeting is an integral part of the financial health of any institution, and, especially, small community hospitals walking on the thin and sharp edge of the sword. In addition to cost-effectiveness, hospitals should focus on hammering down the training program not only limited to surgeons but the entire operating room team. Finally, quite often, a hospital system which acquires the da Vinci should understand that marketing is the key to success for the program [19]. The absence of a marketing plan in place often becomes the reason for the failure of the program [20]. Therefore, research performed well in advance to investigate potential avenues of marketing strategies addressing demography or geographical needs must be well thought out prior to acquiring the system in the need assessment phase. Need Assessment phase is not only limited to investigating and analyzing the need for the da Vinci system (**Figure 1**) but also the initial planning and strategy development phase, so that when the system is acquired, administration and the entire team have a clear vision and direction of how they will be developing the program moving forward.

3. Team building - the cornerstone of a robotic program often neglected

Teams in the operating room have conventionally been trained in traditional open or laparoscopic surgery where the flow of the surgery is largely directed by surgeons. The mere presence of the da Vinci platform in the operating room changes many aspects of surgery as we know it, including the dynamics of the operating room along with the order of events preoperatively, intraoperatively, and postoperatively. In robotic surgery, the surgeon sits on a robotic console almost 5–10 feet away from the patient. The absence of the surgeon at the patient's bedside adds additional complexity and anxiety in the operating room among the team members. These new arrangements, including surgeon console, robotic arms, and robotic tower, require an operating room with a surgical team that is well-trained and understands the intricacies that go along with robotic surgeries, as well as the ability to share the burden of problem-solving and troubleshooting any issues that may arise throughout the process. The robotic platform brings unique challenges for the team. For instance, in nonrobotic surgery, surgeons often communicate with their team by signaling or often using not more than a single word [21]. Many a time, assistants understand the need before the surgeon even utters a word. However, in a robotic procedure, communication involves more detailed and clear instructions like pilots communicating with each other or with a control room, and everything needs to be loud and clear. The team needs to be trained to have effective bilateral communication and acknowledgment of all the instructions given by the surgeon or other way around. While traditional surgery has somewhat painted operating rooms as very strict and technical with the surgeon as the chief of events, the robotics platform enforces more of a team approach with a unique chronology of events. Thus, building an efficient team is very crucial for the success of a robotic program. This aspect can often be overlooked by either the hospital administration, the surgeon, or the operating room team. This may be overlooked because the territory of minimally invasive surgery seems familiar, but there remains the aspect of the robotic platform, which is not so familiar including the change in dynamics of the operating room with the integration of robotics. Therefore, the ability to have a successful robotic program depends not only on a surgeon who is well-versed in these technologies and surgical processes, but also a team made of members who feel like they too are an integral part of the robotic program.

Adoption of properly designed curriculum-based training is extremely important. This training should be subjected to all team members, including console surgeon, anesthesiologist, bedside assistance, assistance holding the uterine manipulator, and circulator. Initial training should include set up, docking, undocking, emergency shut down, and both mechanical and electrical troubleshooting [22]. Further training should be procedure-specific, and surgeons need to be involved in training the staff [23]. Some challenges come into play when trying to effectively build a team capable of performing these robotic procedures correctly and efficiently. For one, the surgeon must play the role of both the leader of the surgical procedure along with the leader who can effectively troubleshoot any problems which may arise through the process and can optimize operating with advanced technology. Moreover, the surgical team, including the surgeon and team members, must be willing to embrace this new technology and new approach to surgery after many years of training and practicing in ways that are totally different. A study published in Harvard Business Review by Edmonson compared 16 institutions that employed a minimally invasive approach to cardiac surgery. This study showed that some of these institutions were better able to use their experience for their advantage than others. The study demonstrated that motivation to learn was the most consistent characteristic with the ability to build a successful team, not the conventional predictors like case volume or experience level [24]. Personality traits of members of a successful team are not limited to openness to change, willingness to seek and elicit feedback, and readiness to recognize when they make a mistake. On the contrary, less successful programs employed leaders who were not as open to change and were not as effective at creating an environment conducive to learning. While this study primarily focused on cardiac surgery, the same parameters should apply to gynecologic procedures [25]. Thus, this idea of team building serves as an important cornerstone in the advancement of robotic procedures in the field of gynecologic surgery.

4. Culture of safety

The Institute of Medicine identifies patient safety as one of the key issues that are critical for health care delivery [26]. Changes to practice patterns that are well-established and proven to be effective always raise concerns about how they affect the safety of the patient. The same is true, to maybe an even higher degree, in the process of implementing complex and advanced technologies like robotic-assisted surgical procedures. These concerns come from healthcare personnel in every aspect of the patients' care, including operating room staff, perioperative nursing staff, anesthesia team members, and many others. While these concerns may be unfounded and unproven, they could affect morale and consequently patient outcomes [27]. Often, many hospitals implement Enhanced Recovery After Surgery (ERAS) program with robotic procedures. Many surgeons discharge robotic hysterectomy in a few hours after surgery. Nursing staff who are traditionally trained to keep minimal invasive surgery patients at least one-night inpatient may feel a little less safe to operate Enhanced Recovery After Surgery (ERAS) program and help to discharge patients home in few hours after major surgery. Studies have found that teamwork and collaboration, meetings to provide opportunities for clarification [28, 29], and staff education [30, 31] are key elements for the success of ERAS, which again supports our argument to develop an adequate culture of safety by proper communications with all stakeholders involved in postoperative care, including patients. Similarly, this has been shown in several studies that have shown that scoring higher on questions about teamwork and better communication/co-ordination is correlated with shorter length of stay and associated postoperative morbidities and mortalities. A study by Hughes et al. highlighted that 40% of US hospital nursing staff think that making changes to make improvements is difficult most of the time or all the time, which is very relevant to the implementation of advanced technologies in medical practice [32]. Recognizing that errors are sometimes inevitable, incorporating nonpunitive error reporting and analysis systems, a platform for open discussion, a willingness to learn from errors, and identifying latent threats are all characteristics of strong cultures of safety.

Three vital organizational factors are responsible for a strong environment of culture of safety: (1) environmental structures and processes within the organization, (2) the attitudes and perceptions of workers, and (3) the safety-related behaviors of individuals [33]. Institute of Medicine (US) Committee on the Work Environment for Nurses and Patient Safety narrated the following essential elements of an effective safety culture. These include a commitment of leadership to safety, empowerment and engagement of all employees in ongoing vigilance, communication, non-hierarchical decision making, constrained improvisation, training, confidential error reporting, fair and just responses to reported errors, reporting near misses as well as errors, etc. [34]. Two major barriers have been identified in adopting culture of safety. First is 'A nursing culture that fosters unrealistic expectations of clinical perfection.' Nurses are trained to believe that there is no alternative to clinical perfection, and error is the result of their carelessness that makes them less than good nurses. Higher standards and error-free care are always appreciated, but when that belief becomes counterproductive, it affects the overall care and goals of any program. Therefore, it is imperative to communicate with nurses that error is a systemic problem and not an individual one. Their minds need to be trained not to think any less of their colleagues when they make errors. Second is 'litigation and regulatory barriers.' Unfortunately, regulatory boards and the court of law or peer review processes at hospitals again reinforce the idea of clinical perfection. Therefore, it is very difficult for nursing staff to deviate from the routine practice and adopt changes that come with new technology. The culture of safety will play a large role in the outcomes of robotic-assisted surgeries, and therefore, it is both necessary and vital to address the changes that come with the implementation of novel technology. To develop a successful robotic program, it is important to implement frequent reviews of outcomes, multidisciplinary discussions, development of parameter-based new postoperative care protocols, and consideration of recommendations and management strategies from all the team members. This is a crucial part of the process of building a gynecologic surgical robotic program, and it requires commitment from members at all levels in the health care delivery system with a strong sense of culture of safety.

5. Learning curve

In 1885, German psychologist Herman Ebbinghaus described the concept of the learning curve, saying, "By a sufficient number of repetitions their final mastery is ensured. [35]" In 1936, Wright endorsed the concept of the learning curve by hypothesizing that by increasing production one achieves perfection and, consequently, requires less time to produce aircrafts. Over 1,200 robotic programs have been established across the United States, with over 1,500 gynecologic surgeons being trained in the technology. Along with this training, there obviously comes a learning curve. This phenomenon is well-established with robotic surgery in all specialties, and multiple studies have been published to discuss the learning curve and minimum cases require to surpass the learning curve [36, 37]. The learning curve could be different for surgeons with advanced surgical skills [38] and variable for different portions of the same surgical procedure [39]. Acquisition and maintenance of a robotic program is a costly venture [16]. Not including initial acquisition, robotic hysterectomies cost roughly $2000 more than laparoscopic hysterectomies. This increased cost difference is attributed to the cost of instruments (Intuitive surgical has restricted the number of instruments in use), the costs of operating room time, costs of staffing, costs of training, and costs of personal egos. Out of these, the learning curve certainly accounts for the costs of increased operating room time, costs of personal egos, costs of the number of instruments used, costs associated with complications, etc. Therefore, before adopting a robotic program, surgeons and hospital administration should have proper understanding of the phenomenon of 'the learning curve," and its implications on the balance sheet of the hospitals. Typically, the learning curve has been described as an S-curve or sigmoid shape (**Figure 2A**). The Y-axis represents learning, and the x-axis represents experience. Classical sigmoid behavior represents an initially slow, then rapid, and subsequently slow improvement [40]. In most medical studies of learning curves, the statistical approach discretizes cases into groups and uses standard statistical methods to compare the variables. This methodology provides the statistical significance values, but it is not always the optimal way to assess the learning curve which is a dynamic process in which improvement occurs on a case-to-case basis.

A sensitive way to portray surgical failures that are indicative of both the early learning curve and the post-learning curve is the cumulative sum failure analysis (CUSUM) [41–43]. This technique not only recognizes time as an important, hidden

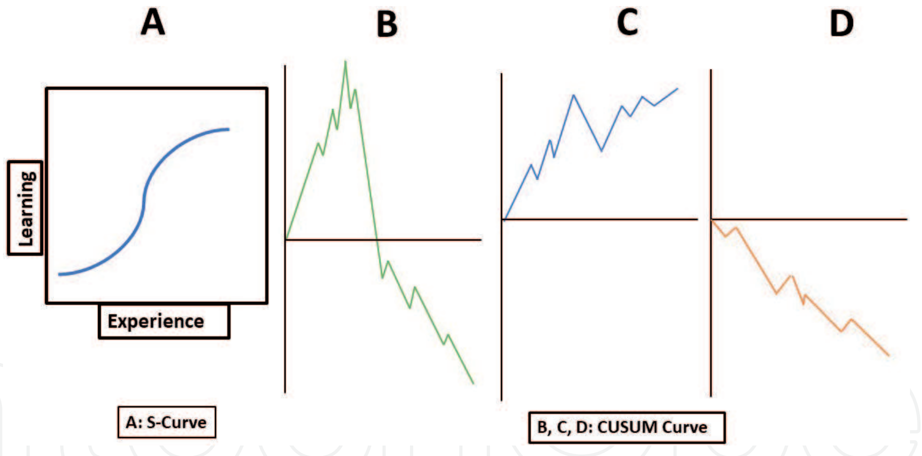

Figure 2.
Learning curve. A - S curve; B, C, D - different type of hypothetical CUSUM curve.

variable in these studies, but it also prevents the decreased statistical significance that can sometimes accompany repeat testing. For these reasons, both the standard statistical method and cumulative sum analysis are recommended to fully assess new teams with accurate and objective feedback. The following formula is used to plot the cumulative sum curve: $Sn = \Sigma(Xi–Xo)$ where $Xi = 0$ means success and $Xi = 1$ means failure. Xo represents the predicted risk of major adverse events. The X-axis portrays the number of cases, while the Y-axis represents the sum of failure. This is shown in the figure (**Figure 2B**). The line that trends above the baseline portrays the learning curve or a performance that does not meet expectations. Contrarily, the line trending toward or below the baseline portrays the performance that is improving or the post-learning curve, respectively. The line trending below the baseline and away from the baseline shows adequate experience or performance that is either better or equivocal. Examples of these graphs are represented in **Figures 2B–D**. **Figure 2A** shows the analysis of a hypothetical CUSUM analysis of any successful procedure as explained above. **Figure 2C** has a curve above and moving away from the baseline. This could represent an example of either an unsuccessful procedure or a surgeon not passing the learning curve. **Figure 2D** shows the curve representing either a surgeon with excellent skills from the beginning or having escaped the learning curve that happens when skillful laparoscopic surgeons start performing robotic cases. The assessment of learning not only plays a critical role in development of an effective robotics program to assess the initial learning curve, but it also provides continued monitoring by assessing the state of the learning curve of the entire division from time-to-time which is a critical part of a robotic program [44].

6. Business perspective and return on investment (ROI)

The most important step in acquiring technology is the financial willingness of administration to invest in advanced technology. Therefore, understanding the business model associated with a robotic program is critical. Unlike other industries, the healthcare industry has not experienced a paradigm shift from long-term strategies to transient gain primarily due to the lengthy process that new medical and surgical advancements must undergo to be accepted as a new standard of care. To keep steady profits, companies employ many strategies. One of the strategies is to reduce costs by increasing production and providing the most cost-effective products to market. They often use the theory of "planned obsolescence" [45] by making products with reduced artificial lifespan and, thereby, get repeat sales. One of the most effective strategies is eliminating the competition, so companies can dictate the prices to their buyers. At present, Intuitive Inc. is the only company that produces viable robotic technology approved for human use and unilaterally decides the production cost, maintenance cost, cost of equipment and other accessories, etc. Therefore, administrators have only limited room to save money by reducing operating time, turn-over time, and the costs associated with readmissions and complications. On average, 150 to 300 cases annually are required for at least six years to offset the initial and ongoing costs of the da Vinci System [46]. **Figure 3** shows five industry-tested steps are important to understand in implementation of a robotic program from a business standpoint. It is also important for administrators to understand that competitive advantage is not sustainable, and therefore, requires an evolution in business strategies over time. Thus, it is important to both monitor and incentivize the upscaling phase along with maximizing both the exploitation and reconfiguration stages to further optimize return on investment (ROI) in advanced surgical technology.

Recently, a study analyzed 180,230 women who underwent laparoscopic or robotic-assisted laparoscopic hysterectomies for either benign or malignant indications (specifically endometrial cancer) from 2006 to 2012 [47]. This study demonstrated that the cost of robotic-assisted hysterectomy remained high, but this cost is offset by increased procedure volume. The use of robotic assisted technology was also found to decrease cost for oncology cases but not in benign gynecological surgeries. The cost difference between hysterectomies performed by three different modalities was analyzed by Bell and colleagues [48]. Data reveals that on average, compared to robotic procedures, the total cost for hysterectomies with staging was approximately 30–40% higher in the procedures completed by laparotomy ($P < .005$), but robotic was 10% more expensive than laparoscopic surgeries (P=NS). It can be hypothesized that during the phase of the learning curve, there would be major cost burdens associated with the time of the operation, turn over time, initial complications, prolonged hospital stays for some cases, conversions to open laparotomy, and overhead costs associated with the initial cost of acquisition.

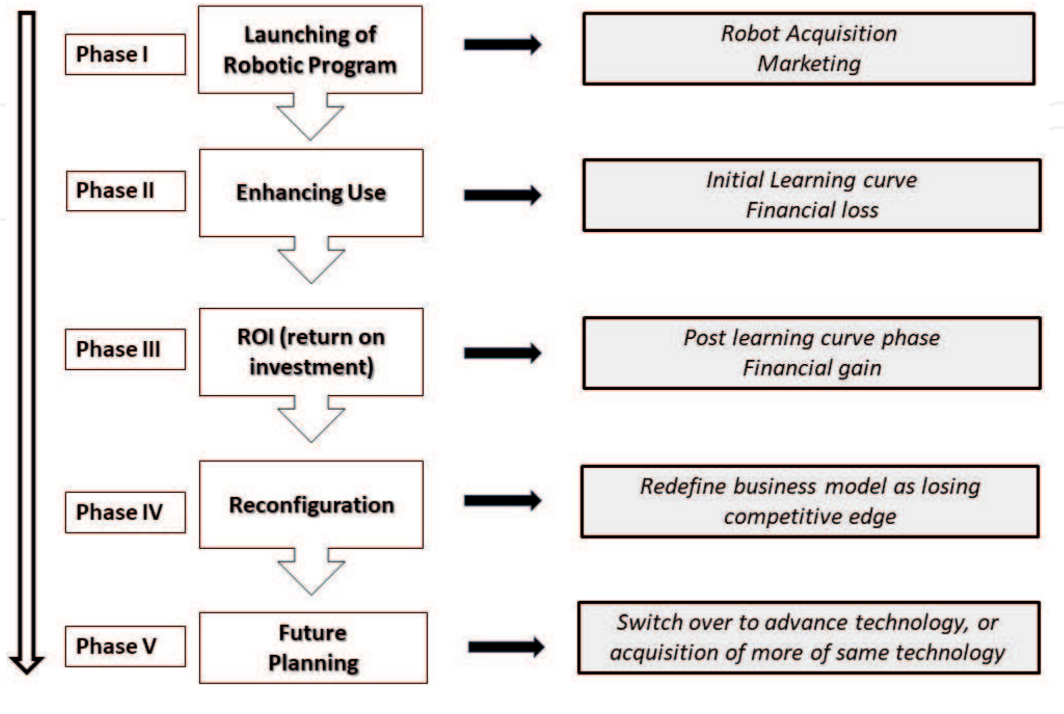

Figure 3.
Five important steps in implementation of a robotic program from business standpoint.

Due to these increased cost burdens, this would potentially minimize the cost advantage of robotic-assisted surgeries over the traditional laparotomy throughout the learning period.

After studying various case studies and industry best practices, we proposed a three-stage business model for a robotic program: 1) Negative earning, 2) Zero sum, and 3) Positive earnings (**Figure 4**). The stage of negative earnings coincides with the initial learning curve stage. Hospital administrators should have strategies in place to overcome the expected financial losses during this time. The most important strategies include low-risk case selections (which would typically offer better outcomes and minimize risks of potential losses) and thereby ensuring excellent patient satisfaction (which would lead to popularity and recognition of the program and strengthen the morale of the surgical staff) and continuous monitoring of the learning curve by various parameters such as operating time (used by surgeons), pre-docking and post-docking time (typically used by nursing and anesthesia), turn over time (time required from the end of one case to the beginning of next case), complications, length of stay, etc. In the zero sum stage, transitioning from the learning stage to the experience stage, it should be vital to market the program with positive patient outcomes. Studies have shown [49] that more than 80% of internet users perform research to use information to make decisions regarding their health care choices, especially surgeries. After the learning curve has been conquered and the program is in the stage of positive earning, administrators can expect to acquire advantages such as expanding the payer mix, which will include more private payers in addition to Medicare and Medicaid. Robotic surgery is associated with an early return to work. Private employers may be more likely to appreciate an employee's early return to work after a surgical procedure. That may provide leverage to hospitals to negotiate contracts that can bring to higher reimbursement for those procedures. Periodically, a review of outcomes and protocols associated with credentialing and recredentialing should always be performed by a multidisciplinary team to maintain safety standards and to avoid 'negligent credentialing claims' which has been increasing in the last decades in the court of law [50]. In current, profit-driven health care economics, disciplined planning, efficient strategy, and forecasting business models are the foundation for successful robotic program.

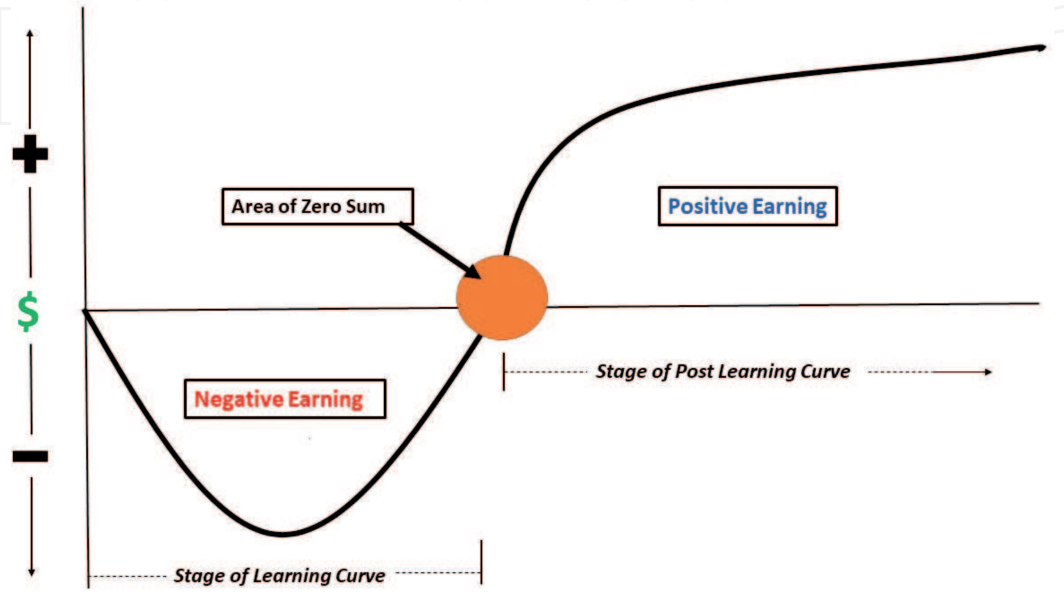

Figure 4.
Hypothetical business model demonstrating sensitivity of revenue stream to learning curve.

7. Conclusion

In conclusion, the adoption of a widespread robotics program for gynecological surgeries has barriers to overcome. The proposed article outlines those barriers and solutions based on literature review and our own experience. It is imperative for hospital administrators and surgeons to understand those barriers to avoid premature frustrations and proper planning for a successful robotic program to avoid the risk of suboptimal patient care and closure of the program before even it starts generating the revenue. With current health care economics, return on investment is an important concept when funds are limited, and, unlike large hospital systems with deep pockets, administrators and surgeons of small community hospital needs to understand above facts and take baby steps accordingly. Robotic platform in gynecology has continued to emerge as a very legitimate challenger to both traditional laparotomy and simple laparoscopic procedures by providing improved ergonomics and maneuvering capabilities. By overcoming the barriers outlined above, there is hope that robotic-assisted procedures will provide another legitimate option to improve outcomes for patients in the future of gynecologic operations.

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